



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/501,566

07/15/2004

Yumiko Uno

Q101072

8263

23373 7590 02/19/2008
SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

EXAMINER

LOCKARD, JON MCCLELLAND

ART UNIT

PAPER NUMBER

1647

MAIL DATE

DELIVERY MODE

02/19/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/501,566	Applicant(s) UNO ET AL.	
	Examiner JON M. LOCKARD	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20,23,24,27 and 28 is/are pending in the application.
- 4a) Of the above claim(s) 3,5-10,12-19,23,24,27 and 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,11 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-20,23,24,27 and 28 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 July 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>7/15/04, 12/9/05</u> | 6) <input checked="" type="checkbox"/> Other: <u>Sequence Alignments</u> |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-4, 11, and 20, drawn to polypeptides of SEQ ID NO:1 and compositions and kits comprising the same, in the reply filed on 26 November 2007 is acknowledged.
2. Claims 3, 5-10, 12-19, 23-24, and 27-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 26 November 2007.
3. The restriction requirement is still deemed proper and is therefore made FINAL.

Status of Application, Amendments, and/or Claims

4. The response filed on 26 November 2007 has been entered in full. Claims 3, 5-10, 12-19, 23-24, and 27-28 are withdrawn from further consideration as discussed *supra*. Therefore, claims 1-20, 23-24, and 27-28 are pending, and claims 1-2, 4, 11, and 20 are the subject of this Office action. It is noted that the elected invention is the polypeptide of SEQ ID NO:1, and the claims have been examined to the extent that they read upon the elected invention.

Priority

5. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file, and the Examiner has acknowledged that "all" copies of the certified copies of the priority documents have been received in this National Stage application. However, should applicant desire to obtain the benefit of foreign priority under 35

Art Unit: 1647

U.S.C. 119(a)-(d) prior to declaration of an interference, a translation of the foreign applications should be submitted under 37 CFR 1.55 in reply to this action.

Information Disclosure Statement

6. The information disclosure statements (IDS) submitted on 15 July 2004 and 09 December 2005 have been considered by the examiner.

Sequence Rules

7. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, the application fails to comply with the requirements of 37 CFR 1.821 through 1.825. Specifically, amino acid sequences appear in Figures 1, 6, 8-10, and 13 without an accompanying sequence identifier (i.e., SEQ ID NO: #). It is noted that if the sequences that appear in the figures are not included in the Sequence Listing, applicant is required to provide (1) a substitute computer readable form (CRF) copy of a "Sequence Listing" which includes all of the sequences that are present in the instant application and encompassed by these rules, (2) a substitute paper copy of that "Sequence Listing", (3) an amendment directing the entry of that paper into the specification, and (4) a statement that the content of the paper and computer readable copies are the same, and, where applicable, include no new matter, as required by 37 C.F.R. § 1.821 through 1.825. The claims and/or instant specification will also need to be amended so that it complies with 37 C.F.R. § 1.821(d) which requires a reference to a particular sequence identifier (i.e., SEQ ID NO: #) be made in the specification and claims wherever a reference is made to that sequence (See M.P.E.P. 2422.04).

Drawings

8. The Drawings are objected to for the following informalities:

9. The drawings are objected to because Figures 1, 6, 8, 9, 10, and 13 disclose amino acid sequences without an accompanying sequence identifier (i.e., SEQ ID NO: #). The SEQ ID NO: may be inserted into the Figure or the Brief Description of the Drawings.

10. Figures 8-10 are objected to because 37 CFR 1.84 states that “[P]artial views intended to form one complete view, on one or several sheets, must be identified by the same number followed by a capital letter”.

11. Corrected drawing sheets are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should *not* be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled “Replacement Sheet” in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

12. The disclosure is objected to because of the following informalities:

13. The use of the trademarks has been noted throughout the Specification (See for example HIGH FIVETM (pg 55, line 3), TRITON X-100TM (pg 58, line 13), POLYSORBATE 80TM (pg 81, line 7), and TWEEN-80TM (pg 97, line 5). Trademarks should be capitalized wherever they appear and should be accompanied by the generic terminology. Applicant is encouraged to review and make appropriate corrections to the specification regarding the misuse of trademarks. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks. Appropriate correction is suggested.

14. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. Applicant is requested to avoid the use of “novel” in the title, as patents are presumed to be novel and unobvious. Appropriate correction is suggested.

Claim Objections

15. Claims 1 and 2 are objected to because of the following informalities: Claims 1 and 2 encompass non-elected inventions, e.g., SEQ ID NO:14 (claims 1 and 2) and SEQ ID NO:104 (claim 1). Appropriate correction is suggested.

Claim Rejections - 35 USC § 101

16. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

17. Claims 1, 2, and 4 are rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter. The claims read on a product of nature in that the claimed compound (a protein or a partial peptide thereof) is not “isolated”. The claims encompass, for example, a polypeptide that has not been removed from the animal or human. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of “isolated” or “purified”. See MPEP 2105.

Claim Rejections - 35 USC § 112, 1st Paragraph (Scope of Enablement)

18. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

19. Claims 1-2, 4, 11, and 20 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for an isolated protein consisting or comprising the amino acid sequence SEQ ID NO:1, does not reasonably provide enablement for an isolated protein comprising the same or substantially the same amino acid sequence as an amino acid sequence represented by SEQ ID NO:1 or a partial peptide thereof, or a protein consisting or comprising an amino acid sequence represented by SEQ ID NO:1. The specification does not enable any

Art Unit: 1647

person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

20. The specification's disclosure is insufficient to enable one skilled in the art to practice the invention as broadly claimed without undue experimentation. The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

21. The claims are drawn quite broadly to a protein comprising the same or substantially the same amino acid sequence as an amino acid sequence represented by SEQ ID NO:1 or a partial peptide thereof, and a protein consisting or comprising an amino acid sequence represented by SEQ ID NO:1. The claims also recite a pharmaceutical composition comprising the protein or partial peptide thereof and a pharmaceutically acceptable carrier, excipient, or diluent, and a kit comprising the protein or partial peptide thereof. While the Specification discloses a protein consisting of the amino acid sequence SEQ ID NO:1 which transports estrone sulfate and dehydroepiandrosterone sulfate, it does not teach a commensurate number of the claimed proteins comprising an amino acid sequence that is substantially the same as SEQ ID NO:1, which the Specification teaches includes an amino acid sequence having at least about 50% homology (See pg 27, lines 11-15). Other than the polypeptide of SEQ ID NO:1, the disclosure

Art Unit: 1647

fails to provide sufficient guidance and information regarding the structural and functional requirements commensurate in scope with what is encompassed by the instant claims. The disclosure has not shown (1) which portions of the protein of SEQ ID NO:1 are critical to the activity of the protein of SEQ ID NO:1; (2) what modifications e.g., substitutions, deletions, or additions) one can make to SEQ ID NO:1 that will result in protein mutants or variants with the same function/activity as the protein of SEQ ID NO:1; and (3) any guidance on how to use the variants of SEQ ID NO:1 which would, based on the language of said claims, encompass both active and inactive variants, especially in the absence of any functional limitations in the claims. The state of the art is such that the relationship between the sequence of a protein and its activity is not well understood and unpredictable, and that certain positions in the sequence are critical to the protein's structure/function relationship and can only tolerate only relatively conservative substitutions or no substitutions.

22. The problem of predicting protein and DNA structure from sequence data and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein and DNA is extremely complex. While it is known that many amino acid substitutions are generally possible in any given protein, the positions within the protein's sequence where such amino acid substitutions can be made with a reasonable expectation of success are limited. Certain positions in the sequence are critical to the protein's structure/function relationship, e.g. such as various sites or regions directly involved in binding, activity and in providing the correct three-dimensional spatial orientation of binding and active sites. These regions can tolerate only relatively conservative substitutions or no substitutions (see Wells, 1990, *Biochemistry* 29:8509-8517; Ngo et al., 1994, *The Protein Folding Problem and Tertiary Structure Prediction*, pp. 492-

Art Unit: 1647

495). However, Applicant has provided little or no guidance beyond the mere presentation of sequence data to enable one of ordinary skill in the art to determine, without undue experimentation, the positions in the protein which are tolerant to change (e.g. such as by amino acid substitutions or deletions), and the nature and extent of changes that can be made in these positions and still retain the activity of the protein of SEQ ID NO:1.

23. Although the Specification outlines art-recognized procedures for producing variants, this is not adequate guidance as to the nature of the active variants that may be constructed, but is merely an invitation to the artisan to use the current invention as a starting point for further experimentation. Even if an active or binding site were identified in the specification, that may not be sufficient, as the ordinary artisan would immediately recognize that an active or binding site must assume the proper three-dimensional configuration to be active, which conformation is dependent upon surrounding residues; therefore substitution of non-essential residues can often destroy activity. The art recognizes that function cannot be predicted from structure alone (Skolnick et al., 2000, Trends in Biotech. 18(1):34-39, especially p. 36 at Box 2; cited by Applicant).

24. Furthermore, claim 11 is drawn to a pharmaceutical composition comprising the protein of claim 1 or the partial peptide thereof. However, the Specification as filed has not disclosed any disease or disorder correlated with the protein of SEQ ID NO:1, therefore, a skilled artisan would not know how to use a pharmaceutical composition comprising the protein of SEQ ID NO:1 or partial peptide thereof. Moreover, the Specification as filed does not provide adequate guidance on how to treat any disease or condition by administration of the protein of SEQ ID

Art Unit: 1647

NO:1, nor is it all predictable that a pharmaceutical composition comprising the protein of SEQ ID NO:1 or partial peptide thereof could be used to treat any disease or condition. With regards to this portion of the rejection, amendment of claim 11 to recite, for example “A composition comprising the protein of claim 1 and a pharmaceutically-acceptable carrier” would be remedial.

25. Due to the large quantity of experimentation necessary to generate the infinite number of derivatives recited in the claims and possibly screen same for activity, the lack of direction/guidance presented in the specification regarding which structural features are required in order to provide activity, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art which establishes the unpredictability of the effects of mutation on protein structure and function, and the breadth of the claims which fail to recite any structural or functional limitations, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Claim Rejections - 35 USC § 112, 1st Paragraph (Written Description)

26. Claims 1-2, 4, 11, and 20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

27. Claims 1-2, 4, 11, and 20 are drawn quite broadly to a protein comprising the same or substantially the same amino acid sequence as an amino acid sequence represented by SEQ ID NO:1 or a partial peptide thereof, and a protein consisting or comprising an amino acid sequence

Art Unit: 1647

represented by SEQ ID NO:1. The claims also recite a pharmaceutical composition comprising the protein or partial peptide thereof and a pharmaceutically acceptable carrier, excipient, or diluent, and a kit comprising the protein or partial peptide thereof. Thus, the claims are drawn to a genus of polypeptides that are defined only by a partial structure.

28. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claims is a partial structure in the form of a recitation of “substantially the same”, which the Specification teaches includes an amino acid sequence having at least about 50% homology (See pg 27, lines 11-15), “represented by”, or “partial peptide”. There is not even identification of any particular portion of the structure that must be conserved.

29. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus. Additionally, the description of one protein species (SEQ ID NO:1) is not adequate written description of an entire genus of functionally equivalent polypeptides, which incorporate all variants, derivatives, and homologs encompassed by the claims.

30. *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the ‘written description’ inquiry, whatever is now claimed” (See page 1117). The specification does not “clearly allow persons of

Art Unit: 1647

ordinary skill in the art to recognize that [he or she] invented what is claimed” (See *Vas-Cath* at page 1116).

31. With the exception of the sequences referred to above, the skilled artisan cannot envision the detailed chemical structure of the encompassed polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

32. One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

33. Therefore, only an isolated protein comprising/consisting the amino acid sequence of SEQ ID NO:1, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 112, 2nd Paragraph

34. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

35. Claims 1, 2, 4, 11, and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

36. Claims 1 and 2 are rejected as indefinite for reciting the phrase “represented by”. Without knowing whether the limitation refers to a protein consisting of the amino acid sequence of SEQ ID NO:1, a protein corresponding to SEQ ID NO:1, or a protein typified by SEQ ID NO:1 (and to what degree, structurally and/or functionally), the metes and bounds of the claim cannot be determined. It is noted that for purposes of examination, the Examiner has interpreted the claims as reading on variants, derivatives, homologs, and orthologs of SEQ ID NO:1.

37. Claims 11 and 20 recite the limitation "the partial peptide" in line 2 of each of the claims. There is insufficient antecedent basis for this limitation in the claims. Claim 1, from which claims 11 and 20 both depend, does not recite a “partial peptide”.

38. Claim 20 is rejected under 35 U.S.C. 112, 2nd paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 20 is considered indefinite because a kit, by definition, must contain 2 or more elements and the interrelationships between the elements must be explicitly stated (see *In re Venezia* 530 F.2d 956 CCPA 1975).

39. Claim 4 is rejected for depending from an indefinite claim.

Claim Rejections - 35 USC § 102

40. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

41. Claims 1-2, 4, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Dawson (U.S. Pat. No. 5,589,358, published 31 December 1996).

42. Dawson teaches an ileal sodium/bile salt cotransporter polypeptide (SEQ ID NO:2) that shares 45% sequence identity to SEQ ID NO:1 of the instant application (See attached sequence alignment) as well as fragments thereof (See column 5, lines 30-45). It is noted that the Examiner has broadly interpreted the claims as reading on variants, derivatives, homologs, and orthologs of SEQ ID NO:1 (See 112(2) rejection *supra*). Furthermore, it is noted that the recitation in claim 20 of, “A kit for screening a compound or its salt that promotes or inhibits the activity of the protein or its salt according to claim 1 or the partial peptide or its salt thereof” has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble

Art Unit: 1647

for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). Thus, the Dawson reference meets all the limitations of claims 1-2, 4, and 20.

43. Claims 1-2, 4, and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Wilganowski et al. (US 2002/0164627, published 07 November 2002, priority date 17 April 2001; previously cited by Examiner).

44. Wilganowski et al. teach a polypeptide (SEQ ID NO:2) that shares 100% sequence identity to SEQ ID NO:1 of the instant application (See attached sequence alignment) as well as fragments thereof (See pg 6[0054]). Furthermore, it is noted that the recitation in claim 20 of, “A kit for screening a compound or its salt that promotes or inhibits the activity of the protein or its salt according to claim 1 or the partial peptide or its salt thereof” has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). Thus, the Wilganowski et al. reference meets all the limitations of claims 1-2, 4, and 20.

Summary

45. No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jon M. Lockard, Ph.D.** whose telephone number is **(571) 272-2717**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Manjunath N. Rao, Ph.D.**, can be reached on **(571) 272-0939**. The fax number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jon M. Lockard, Ph.D.
February 14, 2008

/Jon M Lockard/
Examiner, Art Unit 1647